K002286

MAR 2 2 2001

510(k) Premarket Notification
LDOB Occlusion Balloon Catheter
COOK INCORPORATED

Safety and Effectiveness Information

Submitted By: Mary A. Gossard, M.S.
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235
July 26, 2000

Device:

Trade Name:	LDOB Occlusion Balloon Catheter
Proposed Classification Name:	Catheter, Intravascular Occluding, Temporary
Product Code:	MJN

Predicate Devices:

The LDOB Occlusion Balloon Catheter is similar in terms of intended use, materials of construction, and technological characteristics to the predicate devices reviewed, the Wholey Occlusion Balloon Catheter cleared under document number K772011, the Arrow Intra-Aortic Balloon Catheters cleared under document number K970689, the Baxter Occlusion Fogarty Graft Thrombectomy Catheter, and the Medi-tech (Boston Scientific) Large Occlusion Balloon Catheters.

Device Description

The LDOB Occlusion Balloon Catheters (LDOB6.0-35-100-30 and LDOB6.0-35-100-36) are large diameter balloons to be used for the temporary filling and occlusion of large vessels. The 6 French catheter is crafted of vinyl radiopaque tubing and the balloon is crafted of latex. The catheter consists of two independent lumens. The distal lumen extends the length of the catheter and is used for placing the catheter over a wire guide. The other lumen – the "inflation" lumen – is used to expand and deflate the balloon. Once inflated the balloons reach 30 mm and 36 mm in diameter respectively. Accessories used in conjunction with this device may include, but are not limited to, a needle, a dilator, an introducer sheath, a wire guide, a syringe, dilute contrast media and saline solution.

The distal end of the catheter includes sideports within the balloon for inflation purposes. The endhole of the catheter is 0.038 inches in diameter for use with a .035" wire guide.

The total length of the catheter is 100cm.

Substantial Equivalence

COOK INCORPORATED currently markets a device, the Wholey Occlusion Balloon (K772011), which is believed to be substantially equivalent to the catheter which is subject of this submission. Additional predicate devices reviewed in this submission are the Arrow Intra-Aortic Balloon Catheters cleared under document number K970689, the Baxter Occlusion Fogarty Graft Thrombectomy Catheter, and the Medi-tech (Boston Scientific) Large Occlusion Balloon Catheters.

The indications for use for the above devices include occlusion of large vessels or to arrest the blood flow on a temporary basis in order to eliminate the need for extensive dissection. The similar indications for use and technological characteristics of the LDOB Occlusion Balloon Catheter as compared to the predicate devices supports a determination of substantial equivalency.

Test Data

The LDOB Occlusion Balloon Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- Minimum burst strength
- Compliance Inflation/deflation performance
- Fatigue Bond strength
- Catheter diameter and balloon profile
- Over-the-Arch Torque
- Preparation
- Biocompatibility Tests
- Clinical and Marketing Experience

The results of these tests and information provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a balloon catheter which facilitates large vessel occlusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2001

Ms. April Lavender
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K002286
LDOB Occlusion Balloon Catheter
Regulatory Class: II (two)
Product Code: 74 MJN
Dated: January 24, 2001
Received: January 25, 2001

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

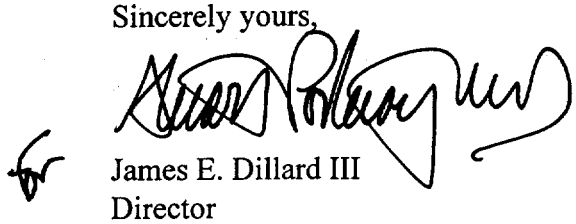
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
LDOB Occlusion Balloon Catheter
COOK INCORPORATED

510(k) Number (if known): K002286

Device Name: LDOB Occlusion (30mm and 36mm) Balloon Catheter

Indications for Use:

For temporary occlusion of large vessels.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

3/21/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K002286